



We create chemistry

April 11, 2016

Document Processing Desk
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Ms. Venus Eagle - PM 1

**SUBJECT: Application for Registration of a New Rodenticide End Use Product,
Selontra® Rodent Bait (EPA File Symbol 7969-XXX)**

Reference: Active Ingredient: Cholecalciferol (BAS 410 I) (unregistered active ingredient)

Dear Ms. Eagle:

BASF Corporation, Company Number 7969, is hereby submitting an application for the registration of **Selontra® Rodent Bait** (BAS 410 06 I), a ready-to-use soft block rodent bait (RB) enrobed in a perforated flavor-permeable wrapper for the control of house mice, Norway Rats, and roof rats. The active ingredient (A.I.) in **Selontra® Rodent Bait** is cholecalciferol, which is not currently registered in the US; however, several rodenticide bait end use products containing cholecalciferol are currently registered in the US by the EPA with the same active ingredient content, use patterns, and A.I. percentage (EPA Reg. Nos. 12455-105, 12455-106, 12455-116, and 12455-117).

Selontra® Rodent Bait will be produced by an "integrated system" process using cholecalciferol derived from a source that is not an EPA-registered pesticide product. Product chemistry data are provided with this submission for the source of active ingredient used in the formulation of **Selontra® Rodent Bait**. An active ingredient data matrix is included with this submission with citation for other studies supporting the source of active ingredient used in this end use product.

The **Selontra® Rodent Bait** product comprises the bait block formulation plus the wrapper, which is made out of a perforated polyolefin film. BASF is producing this end use product in the UK at a facility that is listed in box 2 on the CSF with the name and address of the producer.



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Data included with this submission comprises product chemistry, acute toxicology, and efficacy data for **Selontra®**, the end use product. BASF also generated efficacy data on the pesticide product and the bait for rats and for mice. We are also submitting EU field trial data generated on a substantially similar BASF product, US field trial on the **Selontra®** product, and we are citing aged-out field trial data on previously registered baits with same percent cholecalciferol content.

An inhalation toxicity addendum report is included to explain why BASF believes “If Inhaled” language is not needed on the **Selontra®** proposed label because of the configuration of the delivery system for the product. In addition, a white paper summarizing the efficacy, secondary toxicity, and overall data results for the **Selontra®** product data package, is included with the submission [MRID 49667526]. In some reports, the code “BAS 410 HH I” is used, which is an experimental formulation code that is equivalent to the final formulation code BAS 410 06 I, for **Selontra® Rodent Bait**.

Per conversation with Steve Schaible, PRIA Ombudsman, BASF proposes this application as the primary application, and proposes PRIA category R334 (CR No. 53), “New product; MUP or End use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Selective data citation” with an 11 month decision review time and a fee of \$19,838.

Linked to this action, BASF is simultaneously submitting two additional registration applications at this time as separate packages for two new rodenticide end use consumer products named **TC 411** and **TC 412**. Both products are also produced in “integrated systems” using cholecalciferol, derived from a source that is not an EPA-registered pesticide product. BASF is proposing the secondary PRIA category R334.2 for both of these actions.

Under current electronic guidelines, BASF Corporation is submitting all administrative documents exclusively in electronic (XML) format in lieu of paper copies.

The following documents are enclosed in support of the registration application for **Selontra® Rodent Bait**:

1. EPA Form 8570-1 “Application for Pesticide” for **Selontra® Rodent Bait**;
2. Transmittal document containing information on the studies being submitted in support of the registration application;
3. Basic and Alternates #1-4 Confidential Statements of Formula (CSF) for **Selontra® Rodent Bait** dated March 30, 2016;
4. EPA form 8570-34 Certification with Respect to Data Citation for **Selontra® Rodent Bait**;
5. Data Matrix for Cholecalciferol Technical Material referencing generic and BASF technical data (Agency and Public Use copies);
6. Data Matrix for **Selontra® Rodent Bait** End Use Product data (Agency and Public Use copies);



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7. Proposed **Selontra® Rodent Bait** labeling,
007969-00XXX.20160330.NVA 2015-04-517-0089;
8. Pay.gov PRIA fee payment receipt.

The PRIA fee information has been included in Section II of the EPA Form 8570-1 "Application for Pesticide" and the fee of \$19,838.00 was paid on March 7, 2016 (pay.gov Tracking ID 25QBRR4H, Agency Tracking ID 74973068728).

We sincerely appreciate your attention to this request. If you have any questions or need clarification or further information, I can be reached directly by phone at (919)-547-2697, or by e-mail at christine.keating@basf.com.

Sincerely,

A handwritten signature in cursive script that reads "Christine Keating".

Christine M. Keating
Team Leader, Federal Registrations
Regulatory Affairs
BASF Corporation

Selontra® is a registered trademark of BASF



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|--|
| 1. Company/Product Number BASF Corp./ 7969-XXX | 2. EPA Product Manager Venus Eagle | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Selontra® Rodent Bait | PM# 1 | |
| 5. Name and Address of Applicant (Include ZIP Code) BASF Corporation, Agricultural Products P.O. Box 13528, 26 Davis Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission for application of a new pesticide end-use product registration for product tradename Selontra® Rodent Bait. This submission contains product chemistry, acute toxicology, efficacy data, and directions for use labeling for review by EPA. BASF considers this action a R334 PRIA action, "New end use product with unregistered source of active ingredient, selective data citation," 11 month review, and \$19,838 fee. The PRIA fee was paid on March 7, 2016 with Agency Tracking ID 74973068728. This primary action is linked to two secondary actions (R334.2) submitted concurrently for products TC 411 and TC 412.

If you have any questions or need further clarification, I can be reached by phone at 919-547-2697 or by e-mail at christine.keating@basf.com.

Section - III

| | | | | | |
|--|--|---|-----------------------------|---|---|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | | <input type="checkbox"/> Metal | <input checked="" type="checkbox"/> Plastic |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. 20 g | No. per container 90-500 | If "Yes" Package wgt. | No. per container |
| | | | | | <input type="checkbox"/> Glass |
| | | | | | <input type="checkbox"/> Paper |
| | | | | | Other (Specify) _____ |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container | | 4. Size(s) Retail Container 4 lb - 22 lb | | 5. Location of Label Directions <input checked="" type="checkbox"/> on labeling adhered to container | |
| 6. Manner in Which Label is Affixed to Product | | <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | |

Section - IV

| | | |
|--|--|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Christine Keating | Title Team Leader, Federal Registrations | Telephone No. (Include Area Code) 919-547-2697 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title Team Leader, Federal Registrations | |
| 4. Typed Name Christine Keating | 5. Date March 30, 2016 | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

| | |
|--|--|
| Applicant's/Registrant's Name, Address, and Telephone Number BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. (919)-547-2000 | EPA Registration Number/File Symbol 7969-xxx |
| Active Ingredient(s) and/or representative test compound(s) Cholecalciferol | Date March 30, 2016 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Rodenticide, indoor/outdoor | Product Name Selontra® Rodent Bait (BAS 410 06 I) |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

| | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|---------------|------------------------|---|
| Signature | Date March 30, 2016 | Typed or Printed Name and Title Christine M. Keating, Product Registration Manager |
|---------------|------------------------|---|



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DATA MATRIX

| | | |
|--|---|-------------|
| Date 30 March 2016 | EPA Reg No./File Symbol 7969-XXX | Page 1 of 8 |
| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---------------------------------------|-------------|-------------------------|--------|------|
| Misc. | Generic Active Ingredient Data | Cite-all | Bell Laboratories, Inc. | OLD | 1 |
| | | | | | |
| | EFFICACY OF VERTEBRATE CONTROL AGENTS | | | | |
| 96-10 | Commensal rodenticides | 141447 | Bell Laboratories, Inc. | OLD | |
| | | 145792 | Bell Laboratories, Inc. | OLD | |
| | | 151406 | Bell Laboratories, Inc. | OLD | |
| | | 152231 | Bell Laboratories, Inc. | OLD | |
| | | 152785 | Bell Laboratories, Inc. | OLD | |
| | | 153067 | Bell Laboratories, Inc. | OLD | |
| | | 153070 | Bell Laboratories, Inc. | OLD | |

| | | |
|------------------------------------|---|------------------------|
| Signature <i>Christine Keating</i> | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
|------------------------------------|---|------------------------|



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| Date 30 March 2016 | EPA Reg No./File Symbol 7969-XXX | Page 2 of 8 |
| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|-------------------------|--------|------|
| | | 153071 | Bell Laboratories, Inc. | OLD | |
| | | 153432 | Bell Laboratories, Inc. | OLD | |
| | | 154652 | Bell Laboratories, Inc. | OLD | |
| | | 155742 | Bell Laboratories, Inc. | OLD | |
| | | 40325601 | Bell Laboratories, Inc. | OLD | |
| | | 40325602 | Bell Laboratories, Inc. | OLD | |
| | | 40325603 | Bell Laboratories, Inc. | OLD | |
| | | 40325604 | Bell Laboratories, Inc. | OLD | |
| | | 40325605 | Bell Laboratories, Inc. | OLD | |
| | | 40819801 | Bell Laboratories, Inc. | OLD | |

| | | |
|------------------------------------|---|------------------------|
| Signature <i>Christine Keating</i> | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
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| Date 30 March 2016 | EPA Reg No./File Symbol 7969-XXX | Page 3 of 8 |
| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-------------------------|--------|------|
| | | 40819802 | Bell Laboratories, Inc. | OLD | |
| | | 40897701 | Bell Laboratories, Inc. | OLD | |
| | | 42067002 | Bell Laboratories, Inc. | OLD | |
| | Palatability – Mouse | 49667508 | BASF Corporation | Own | |
| | Palatability – Rat | 49667509 | BASF Corporation | Own | |
| | Laboratory Efficacy – Placepack – Rat | 49667517 | BASF Corporation | Own | |
| | Laboratory Efficacy – Placepack – Mouse | 49667518 | BASF Corporation | Own | |
| | Laboratory Efficacy – Unwrapped – Rat | 49667519 | BASF Corporation | Own | |
| | Laboratory Efficacy – Unwrapped – Mouse | 49667520 | BASF Corporation | Own | |
| | Laboratory Efficacy – Unwrapped – Rat | 49667524 | BASF Corporation | Own | |

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|------------------------------------|---|------------------------|
| Signature <i>Christine Keating</i> | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
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| Date 30 March 2016 | EPA Reg No./File Symbol 7969-XXX | Page 4 of 8 |
| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|------------------|--------|------|
| | Laboratory Efficacy – Unwrapped – Mouse | 49667525 | BASF Corporation | Own | |
| | Selontra® Rodent Bait: Efficacy, Secondary Toxicity, and Overall Data Understanding White Paper | 49667526 | BASF Corporation | Own | |
| | Field Trial Efficacy – Rat – Ken Probert Timber, Oswestry, Shropshire, England | 49667527 | BASF Corporation | Own | |
| | Field Trial Efficacy – Mouse – Cricket Farm Food Store, Ellesmere, Shropshire, England | 49667528 | BASF Corporation | Own | |
| | Field Trial Efficacy – Rat – Frankton Grange Stud Farm, Ellesmere, Shropshire, England | 49667529 | BASF Corporation | Own | |
| | Field Trial Efficacy – Rat – New Crickett Farm, Ellesmere, Shropshire, England | 49667530 | BASF Corporation | Own | |
| | Field Trial Efficacy – Rat – Ken Probert Timber, Oswestry, Shropshire, England | 49667531 | BASF Corporation | Own | |
| | Field Trial Efficacy – Mouse – Days Reupholstery, Oswestry, Shropshire, England | 49667532 | BASF Corporation | Own | |
| | Field Trial Efficacy – Mouse – Old Crickett Storage Units, Oswestry, Shropshire, England | 49667533 | BASF Corporation | Own | |
| | Field Trial Efficacy – Mouse – The Old Piggeries At Pentredaffydd Farm, Oswestry, Shropshire, England | 49667534 | BASF Corporation | Own | |

| | | |
|------------------------------------|---|------------------------|
| Signature <i>Christine Keating</i> | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
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| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|--|-------------|------------------|--------|------|
| | Field Trial Efficacy – Mouse – Pentredaffydd Farm, Oswestry, Shropshire, England | 49667535 | BASF Corporation | Own | |
| | Field Trial Efficacy – Rat – Park Mill Farm, Oswestry, Shropshire, England | 49667536 | BASF Corporation | Own | |
| | Field Trial Efficacy – Rat – Witte Farm, Warendorf, Germany | 49667537 | BASF Corporation | Own | |
| | Field Trial Efficacy – New Orleans, USA | 49667538 | BASF Corporation | Own | |
| SERIES 830 | PRODUCT PROPERTIES TEST GUIDELINES | | | | |
| | Product Identity, Composition, and Analysis Test Guidelines | | | | |
| 830.1550 (61-1) | Product identity and composition | 49667516 | BASF Corporation | Own | |
| 830.1600 (61-2) | Description of materials used to produce the product | 49667516 | BASF Corporation | Own | |
| 830.1620 (61-2) | Description of production process | 49667516 | BASF Corporation | Own | |
| 830.1650 (61-2) | Description of formulation process | 49667516 | BASF Corporation | Own | |

| | | |
|------------------------------------|---|------------------------|
| Signature <i>Christine Keating</i> | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
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| Date 30 March 2016 | EPA Reg No./File Symbol 7969-XXX | Page 6 of 8 |
| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|--|-------------|------------------|--------|------|
| 830.1670 (61-3) | Discussion of formation of impurities | 49667516 | BASF Corporation | Own | |
| 830.1700 (62-1) | Preliminary analysis | 49667516 | BASF Corporation | Own | |
| | | 49667522 | BASF Corporation | Own | |
| 830.1750 (62-2) | Certified limits | 49667516 | BASF Corporation | Own | |
| 830.1800 (62-3) | Enforcement analytical method | 49667516 | BASF Corporation | Own | |
| | | 49667522 | BASF Corporation | Own | |
| | Physical/Chemical Properties Test Guidelines | | | | |
| 830.6302 (63-2) | Color | 49667505 | BASF Corporation | Own | |
| 830.6303 (63-3) | Physical state | 49667505 | BASF Corporation | Own | |
| 830.6304 (63-4) | Odor | 49667505 | BASF Corporation | Own | |

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|------------------------------------|---|------------------------|
| Signature <i>Christine Keating</i> | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
|------------------------------------|---|------------------------|



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| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|------------------|--------|------|
| 830.6314 (63-14) | Oxidation/reduction: chemical incompatibility | 49667507 | BASF Corporation | Own | |
| 830.6315 (63-15) | Flammability | 49667521 | BASF Corporation | Own | |
| 830.6316 (63-16) | Explosibility | 49667521 | BASF Corporation | Own | |
| 830.6317 (63-17) | Storage stability | 49667505 | BASF Corporation | Own | |
| | | 49667506 | BASF Corporation | Own | |
| 830.6320 (63-20) | Corrosion characteristics | 49667505 | BASF Corporation | Own | |
| 830.6321 (63-21) | Dielectric breakdown voltage | 49667521 | BASF Corporation | Own | |
| 830.7000 (63-12) | pH | 49667505 | BASF Corporation | Own | |
| 830.7300 (63-7) | Density/relative density/bulk density | 49667505 | BASF Corporation | Own | |
| 830.7370 (63-10) | Dissociation constants in water | 49667521 | BASF Corporation | Own | |

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| Signature <i>Christine Keating</i> | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
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| Date 30 March 2016 | EPA Reg No./File Symbol 7969-XXX | Page 8 of 8 |
| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|--------------------------------|-------------|------------------|--------|------|
| SERIES 870 | HEALTH EFFECTS TEST GUIDELINES | | | | |
| | Acute Toxicity Test | | | | |
| 870.1100 (81-1) | Acute oral toxicity | 49667510 | BASF Corporation | Own | |
| 870.1200 (81-2) | Acute dermal toxicity | 49667511 | BASF Corporation | Own | |
| 870.1300 (81-3) | Acute inhalation toxicity | 49667512 | BASF Corporation | Own | |
| | | 49667523 | BASF Corporation | Own | |
| 870.2400 (81-4) | Acute eye irritation | 49667513 | BASF Corporation | Own | |
| 870.2500 (81-5) | Acute dermal irritation | 49667514 | BASF Corporation | Own | |
| 870.2600 (81-6) | Skin sensitization | 49667515 | BASF Corporation | Own | |

Note 1: BASF is citing generic active ingredient data on file for cholecalciferol, submitted by Bell Laboratories, Inc. between 1981 and 1993.

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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|-------------------------|--------|------|
| | | | Bell Laboratories, Inc. | OLD | 1 |
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| | | | Bell Laboratories, Inc. | OLD | |
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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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| | | | Bell Laboratories, Inc. | OLD | |
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| | | | BASF Corporation | Own | |
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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|------------------|--------|------|
| | | | BASF Corporation | Own | |
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| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|------------------|--------|------|
| | | | BASF Corporation | Own | |
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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|------------------|--------|------|
| | | | BASF Corporation | Own | |
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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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| | | | BASF Corporation | Own | |
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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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| | | | BASF Corporation | Own | |
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| | | | BASF Corporation | Own | |

Note 1: BASF is citing generic active ingredient data on file for cholecalciferol, submitted by Bell Laboratories, Inc. between 1981 and 1993.

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| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|--|-------------|-------------------------|--------|------|
| Misc. | Generic Active Ingredient Data | Cite-all | Bell Laboratories, Inc. | OLD | 1 |
| | | | | | |
| SERIES 830 | PRODUCT PROPERTIES TEST GUIDELINES | | | | |
| | Product Identity, Composition, and Analysis Test Guidelines | | | | |
| 830.1550 (61-1) | Product identity and composition | 49667501 | BASF Corporation | Own | |
| 830.1600 (61-2) | Description of materials used to produce the product | 49667501 | BASF Corporation | Own | |
| 830.1620 (61-2) | Description of production process | 49667501 | BASF Corporation | Own | |
| 830.1670 (61-3) | Discussion of formation of impurities | 49667501 | BASF Corporation | Own | |
| 830.1700 (62-1) | Preliminary analysis | 49667501 | BASF Corporation | Own | |
| 830.1750 (62-2) | Certified limits | 49667501 | BASF Corporation | Own | |

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| Signature  | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|------------------|--------|------|
| 830.1800 (62-3) | Enforcement analytical method | 49667501 | BASF Corporation | Own | |
| | Physical/Chemical Properties Test Guidelines | | | | |
| 830.6302 (63-2) | Color | 49667502 | BASF Corporation | Own | |
| 830.6303 (63-3) | Physical state | 49667502 | BASF Corporation | Own | |
| 830.6304 (63-4) | Odor | 49667502 | BASF Corporation | Own | |
| 830.6313 (63-13) | Stability to normal & elevated temperatures, metals, and metal ions | 49667502 | BASF Corporation | Own | |
| | | 49667504 | BASF Corporation | Own | |
| 830.6315 (63-15) | Flammability | 49667502 | BASF Corporation | Own | |
| 830.6316 (63-16) | Explodability | 49667502 | BASF Corporation | Own | |
| | | 49667503 | BASF Corporation | Own | |

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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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| 830.7000 (63-12) | pH | 49667502 | BASF Corporation | Own | |
| 830.7050 | UV/visible absorption | 49667502 | BASF Corporation | Own | |
| 830.7200 (63-5) | Melting point/melting range | 49667502 | BASF Corporation | Own | |
| 830.7220 (63-6) | Boiling point/boiling range | 49667502 | BASF Corporation | Own | |
| 830.7300 (63-7) | Density/relative density/bulk density | 49667502 | BASF Corporation | Own | |
| 830.7370 (63-10) | Dissociation constants in water | 49667521 | BASF Corporation | Own | |
| 830.7550 (63-11) | Partition coefficient (<i>n</i> -octanol/water), shake flask method | 49667502 | BASF Corporation | Own | |
| 830.7840 (63-8) | Water solubility: column elution method; shake flask method | 49667502 | BASF Corporation | Own | |
| 830.7950 (63-9) | Vapor pressure | 49667502 | BASF Corporation | Own | |

Note 1: BASF is citing generic active ingredient data on file for cholecalciferol, submitted by Bell Laboratories, Inc. between 1981 and 1993.

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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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DATA MATRIX

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| Date 30 March 2016 | EPA Reg No./File Symbol 7969-XXX | Page 2 of 3 |
| Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528 | Product Selontra® Rodent Bait (BAS 410 06 I) Technical Material Data Matrix | |
| Ingredient Cholecalciferol ((5Z,7E)-9,10-secocholesta-5,7,10 (19)-trien-3β-ol) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|------------------|--------|------|
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| Signature | Name and Title Christine Keating Team Leader, Federal Registrations | Date March 30, 2016 |
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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Note 1: BASF is citing generic active ingredient data on file for cholecalciferol, submitted by Bell Laboratories, Inc. between 1981 and 1993.

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This page and all subsequent pages are for the complete label. {Note to PM: Bold Italicized text enclosed in “{ }” is information for the reviewer and not part of the label. [Bracketed information is optional text.] Text separated by “/” denotes and/or options.}

Selontra® Rodent Bait

This product may only be used inside and within 100 feet of buildings or inside of transport vehicles (aircraft, ships, trains, and trucks) and for all burrow baiting.

Kills Rats and Mice

Kills House Mice, Norway Rats, and Roof Rats

- Controls rats and mice including strains resistant to anticoagulants
- Delayed stop-feed action for fast colony control
- Soft Bait formula for fast acceptance]

Read the entire label before using this product. Follow all **Directions For Use** and **Precautionary Statements**. Use only for the sites, pests, and application methods described on this label.

| | |
|-------------------------------------|----------------|
| ACTIVE INGREDIENT: | |
| Cholecalciferol | 0.075% |
| OTHER INGREDIENTS: | <u>99.925%</u> |
| TOTAL: | 100.000% |

EPA Reg. No. 7969-XXX

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN CAUTION/PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

Refer to full label for **First Aid, Precautionary Statements, Directions For Use, Conditions of Sale and Warranty,** and state-specific use site restrictions.

In case of an emergency endangering life or property involving this product, call day or night 1-800-832-HELP (4357).

NET WEIGHT:

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| FIRST AID | |
|--|---|
| If swallowed | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • DO NOT induce vomiting unless told to do so by a poison control center or doctor. • DO NOT give anything to an unconscious person. |
| If in eyes | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes; then continue rinsing. • Call a poison control center or doctor for treatment advice. |
| If on skin | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice. |
| <p>This product contains Bitrex® to help prevent accidental human consumption.</p> <p>Note to Physician: Cholecalciferol causes hypercalcemia. Treat symptomatically. Treatment would include a low calcium diet, a high salt and fluid intake, and avoidance of exposure to sunlight. Monitoring serum calcium levels may aid treatment. Cortisone has been used successfully in some cases (reference, AMA Drug Evaluations, Third Edition (1977), Chapter 16, pp. 248-251).</p> <p>Treatment for Pet or Non-target Animal Poisoning: Call veterinarian immediately if a pet or other non-target animal consumes this product.</p> <p>Note to Veterinarians: Calcium Mobilizer Cholecalciferol: For animals ingesting bait, induce vomiting by using hydrogen peroxide or administration of activated charcoal with a cathartic. If clinical signs develop, treatment consisting of saline diuresis combined with the use of furosemide, corticosteroids, and phosphate binders are recommended. Calcitonin or pamidronate may be needed for animals that remain hypercalcemic despite symptomatic treatments.</p> | |
| HOTLINE NUMBER | |
| <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact BASF Corporation for emergency medical treatment information: 1-800-832-HELP (4357).</p> | |

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION. Harmful if swallowed or absorbed through skin. Keep away from children, domestic animals, and pets. Keep away from food, drink, and animal feedstuffs. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear the following: socks, shoes, and gloves.

NOTE: Any person who retrieves rodent carcasses or unused bait following application of this product must wear gloves.

User Safety Requirements

Follow the manufacturer’s instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

This product is toxic to fish, birds, and other wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon rodents or other animals that have eaten this bait.

DO NOT apply this product directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark.

Directions For Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT expose children, pets, or non-target animals to rodenticides. To help prevent accidents:

1. Store unused product in original container out of reach of children and pets.
2. **DO NOT** eat, drink, or smoke while using this product.
3. Make applications in areas out of the reach of children, pets, domestic animals, and non-target wildlife, or place bait in tamper-resistant bait stations. Stations must be resistant to destruction by dogs and by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from bait stations when lifted, units must be secured or otherwise immobilized. Stronger bait stations are needed in areas open to hooved livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
4. Dispose of product container and unused, spoiled, or unconsumed bait as specified on this label.

NOTE: Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait.

Use Restrictions

This product may only be used to control house mice, Norway rats, and roof rats. This product may only be used inside and within 100 feet of buildings or inside of transport vehicles (aircraft, ships, trains, and trucks) and for all burrow baiting. Examples:

- In and around homes and other permanent or temporary residences, industrial and commercial buildings, and similar man-made structures;
- In and around agricultural buildings, including but not limited to swine, poultry, cattle, equine and dairy facilities; warehouses; food storage areas and food processing facilities;
- In and around docks and port or terminal buildings, public buildings, trash receptacles, transport vehicles (aircraft, ships, trains, and trucks), and alleys.

NOTE: This product is not approved for broadcast baiting.

DO NOT place near or inside ventilation duct openings.

DO NOT contaminate feedstuffs, food, food or feed handling equipment, milk or meat handling equipment, surfaces that come into direct contact with food, or water. When used in USDA inspected facilities, this product must be applied in tamper-resistant bait stations.

DO NOT sell this product in individual containers holding less than 4 pounds of bait. It is illegal to sell bait blocks individually.

Application Instructions

Selection of Treatment Areas: Determine areas where rats or mice will most likely find and consume the bait. These areas are typically along walls, near gnawed openings or burrows, in corners and concealed places, and other locations where signs of rats or house mice have been observed. Protect bait from rain and snow. Remove as many alternative food sources as possible to prevent competition with the bait.

Monitoring and Maintenance Baiting for House Mice and Norway/Roof Rats: For monitoring rodent activity and protecting sites of interest, use tamper-resistant bait stations in accordance with this label, and use 1 to 4 soft blocks per placement. Position bait stations at intervals of 15 to 50 feet. Replenish bait as needed to maintain an uninterrupted supply. For stations that show activity of Norway/roof rats, up to 8 soft blocks per placement can be used.

Baiting Treatments for Infested Areas: Be sure to provide enough bait for the population; under-baiting may result in failure to control the infestation. This product may be applied away from structures in bait stations, secured as specified on this label.

NOTE: Bait stations are mandatory for outdoor above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait.

- **House Mice:** Use up to 2 soft blocks per placement at intervals of 3 to 6 feet. Two soft blocks per placement may be used at points of high mouse activity. Maintain an uninterrupted supply of bait for 15 days or until there are no longer signs of recent feeding on bait.
- **Norway Rats and Roof Rats:** Use up to 8 soft blocks per placement at intervals of 15 to 30 feet. When using bait stations, use 1 to 8 soft blocks per bait station at intervals of 15 to 50 feet. Bait may only have to be placed and maintained in an uninterrupted supply for 7 days to achieve control, provided sufficient bait relative to the size of the infestation is placed on day 1 of the treatment. To better secure the bait in "rack styled" or "press and secure" soft bait holders, the wrapper may be removed. Wear gloves when separating wrapper from bait.
- **Burrow Baiting (Norway/Roof Rats Only):** This product may be applied to **active** rodent burrows to control Norway/roof rats within or beyond 100 feet of buildings and manmade structures that are vulnerable to harboring or attracting rodent infestations. Efforts should be made to remove food trash, garbage, clutter and debris. Bait must be placed no less than 6 inches into active burrows. Do not broadcast bait.

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Bait Placement Follow-up: To ensure optimum control in the shortest time achievable, inspect bait placements 1 to 2 days after the first bait placement and continue inspections regularly. If a bait placement is completely consumed, double the amount of bait at that placement (up to 4 blocks per placement for house mice and up to 8 blocks per placement for Norway/roof rats). If an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results. Where a continuous source of infestation is present, establish permanent bait stations and replenish bait as needed.

STORAGE AND DISPOSAL

DO NOT contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store only in original container in a cool, dry place inaccessible to children and pets and away from items with an odor that might negatively impact the palatability of the bait. Keep container closed and away from other chemicals.

Pesticide Disposal

Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility. If these wastes cannot be disposed of according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.

Container Handling

Non-refillable container. DO NOT reuse or refill this container. Offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities. **DO NOT** burn, unless allowed by state and local ordinances.

In Case of Emergency

In case of large-scale spill of this product, call:

- CHEMTREC 1-800-424-9300
- BASF Corporation 1-800-832-HELP (4357)

In case of medical emergency regarding this product, call:

- Your local doctor for immediate treatment
- Your local poison control center (hospital)
- BASF Corporation 1-800-832-HELP (4357)

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Conditions of Sale and Warranty

The **Directions For Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as environmental conditions, presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of BASF CORPORATION ("BASF") or the Seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer. BASF warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions For Use**, subject to the inherent risks, referred to above. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW: (A) BASF MAKES NO OTHER WARRANTIES EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY, (B) BUYER'S EXCLUSIVE REMEDY AND BASF'S AND SELLER'S EXCLUSIVE LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THE PRODUCT, AND (C) BASF AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.** BASF and the Seller offer this product, and the Buyer and User accept it, subject to these **Conditions of Sale and Warranty** which may be varied only by agreement in writing signed by a duly authorized representative of BASF. PCS915

Selontra is a registered trademark of BASF.

Bitrex is a registered trademark of Macfarlan Smith.

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BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709



We create chemistry

This page is for the bait block label. {Note to PM: Bold Italicized text enclosed in “{}” is information for the reviewer and not part of the label. [Bracketed information is optional text.] Text separated by “/” denotes and/or options.}

Selontra® Rodent Bait

ACTIVE INGREDIENT:

| | |
|----------------------|--------|
| Cholecalciferol..... | 0.075% |
|----------------------|--------|

OTHER INGREDIENTS: 99.925%

TOTAL:..... 100.000%

EPA Reg. No. 7969-XXX

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

CAUTION: See full label for directions for use and precautions.

2016-05-520-XXXX

NET WEIGHT:

BASF Corporation
Research Triangle Park, NC

Alternate Caution Language:

See [full label][outer][package][pail][bucket][bag][carton][station]
for complete directions for use and precautionary statements.

Optional Hot-line:

1-800-832-HELP (4357)

Optional Statements:

Product of UK

It is illegal to sell these bait blocks individually.

Christi Keating

To: Robin N Payne
Subject: RE: Pay.gov Payment Confirmation: PRIA Service Fees

From: notification@pay.gov [mailto:notification@pay.gov]
Sent: Monday, March 07, 2016 12:16 PM
To: Robin N Payne <robin.payne@basf.com>
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25QBRR4H
Agency Tracking ID: 74973068728
Transaction Type: Sale
Transaction Date: 03/07/2016 12:15:46 PM EST

Account Holder Name: John J Arthur

Transaction Amount: \$19,838.00
Card Type: MasterCard
Card Number: *****8166

Registration Number:
Company Name: BASF Corporation
Company Number: 7969
Action Code: R334

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.